3/1/99

K984597

Summary of Safety and Effectiveness for
Cutinova® cavity - K984597

This 510(k) is being submitted for a modification to Cutinova cavity that was originally cleared for sale in the U.S. in 1995 (K952526)

Cutinova cavity is a polyurethane dressing that is indicated for the management of deep secondary healing wounds. The current modification involves a change in the material used to make the urethane from an aromatic diisocyanate to an aliphatic diisocyanate and does not affect the indications for use.

Biological tests were done in accordance with ISO 10993 and showed no negative effects for the modified Cutinova cavity. Performance characteristics were also comparable to the currently marketed product. In addition, a very small amount of α-Tocopherol was added to improve the thermal stability of the product.

Based on safety information in international data bases, biological testing and performance characteristics, it can be concluded that the modified Cutinova cavity is substantially equivalent to the current legally marketed Cutinova cavity.

Dated: February 9, 1999

Prepared by: Angelo Pereira
Manager, Regulatory Affairs
Beiersdorf-Jobst Inc.
5825 Carnegie Boulevard
Charlotte, N.C. 28209

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 1999

Mr. Angelo Pereira
Beiersdorf-Jobst, Inc.
5825 Carnegie Boulevard
Charlotte, North Carolina 28209-4633

Re: K984597
Trade Name: Cutinova Cavity Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: December 23, 1998
Received: December 28, 1998

Dear Mr. Pereira:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosures) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled for use on third degree burns.

2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. This device may not be labeled as a treatment or a cure for any type of wound.

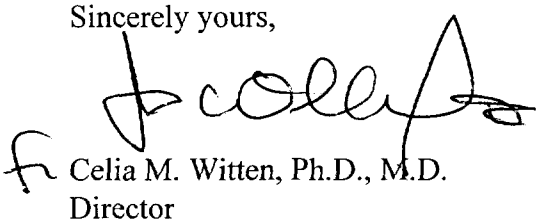
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597,or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K984597

510(k) Number (if known):_____

Device name: **Cutinova cavity**

Indications For Use:

Cutinova cavity is indicated for the management of deep secondary healing wounds such as:

Cavity wounds
Stage III and IV pressure ulcers
Deep leg ulcers
Excisions
Post-op wound dehiscence

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over The Counter Use_____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984597

K984597

510(k) Number K984597

Device name: **Cutinova cavity**

Indications For Use: Over-the-Counter

Cutinova cavity may be used under the direction of a health care professional for the management of deep secondary healing wounds such as:

Cavity wounds
Stage III and IV pressure ulcers
Deep leg ulcers
Excisions
Post-op wound dehiscence

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____
(Per 21 CFR 801.109)

OR Over The Counter Use X

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984597